

COMMENTS

Upon entry of this amendment, claims 29-62 will be pending. Claim 29 is amended herein and claim 62 is added. The amendments to the claims presented in this Response do not add new matter. The amendment to claim 29 and newly added claim 62 are supported for example by figure 2A.

In response to the Requirement for Restriction mailed September 27, 2002, Applicants provisionally elect with traverse, Group I, consisting of 29-48 and 54, drawn to polynucleotides, vectors, and a cell for the polynucleotide directed biosynthesis of the polypeptide, and a pharmaceutical composition that includes the polynucleotide. It is submitted that new claim 62 should be included within Group I. Furthermore, in response to the requirement in the pending Office Action that the Applicants elect a single disclosed polynucleotide, Applicants provisionally elect with traverse, a nucleic acid molecule that includes a nucleic acid molecule encoding the polypeptide having the amino acid sequence of SEQ ID NO:2 (Claim 29(a)). With respect to the requirement that Applicants elect a host, Applicants elect with traverse, "isolated cells and preparations thereof" (class 435, subclass 252.3 and 325; Office Action, Pg. 5). Pending claims 29-31, 43, 44-48, and newly added claim 62 read on the elected species.

Applicants respectfully request joinder of polynucleotide species. The Office Action requires that Applicants elect a single disclosed polynucleotide. To be considered distinct inventions that lack unity of invention, species must not share commonality of operation, function, or effect. MPEP 806.04(e).

The pending claims should not be restricted to a single disclosed polynucleotide sequence because the polynucleotides of the invention share commonality of operation function, and effect. The present invention provides the polynucleotide and polypeptide sequences of human and murine APGD1 (also referred to as AIRE), and mutant forms of human APGD1. Since all of the disclosed polynucleotide sequences are directed to a

polynucleotide that encodes the APGD1 protein, they have commonality of operation, function, and effect (i.e. they encode proteins that cosegregate in mutated form with Autoimmune Polyendocrinopathy Candidiasis Ectodermal Dystrophy (APECED)). Therefore, the species are not distinct species with distinct operation, function, and effect, but, rather, are polynucleotides that encode an APGD1 protein, or mutant form thereof. Accordingly, Applicants respectfully request joinder of the polynucleotide species. Also Applicants request rejoinder of newly added claim 62 because SEQ ID NO:1 "comprises" a nucleic acid molecule of provisionally elected claim 29(a).

If it is maintained that a polynucleotide species must be elected, Applicants provisionally elect, as indicated above, with traverse, a nucleic acid molecule that includes a nucleic acid molecule encoding the polypeptide having the amino acid sequence of SEQ ID NO:2. However, Applicants also respectfully request that if claims directed at the provisionally elected nucleic acid molecule are allowed, claims directed at a nucleic acid molecule that includes a nucleic acid molecule having the nucleotide sequence of a portion of SEQ ID NO:1 that encodes a polypeptide of SEQ ID NO:2 (See e.g., clause b of claim 29) be rejoined with the elected polynucleotide. This request is based on the fact that a nucleic acid molecule that includes a nucleic acid molecule having the nucleotide sequence of a portion of SEQ ID NO:1 that encodes a polypeptide of SEQ ID NO:2, is encompassed within the provisionally elected polynucleotide species.

Regarding the requirement that a host be elected, as indicated above, Applicants with traverse, elect "isolated cells and preparations thereof" (Office Action, pg. 5).